

Practitioner's Docket No. MPI00-438P1RM

### REMARKS / ARGUMENTS

Claims 76-82 are presently pending and under consideration.

#### Rejection of Claims 76-82 under 35 USC §101 Should Be Withdrawn

Claims 76-82 were rejected under 35 USC §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The examiner asserts that no substantial utility is asserted which is specific to the invention, nor is a relationship to any specific disease taught.

Applicants respectfully traverse the rejection and submit that disclosed utilities for the claimed nucleic acids which are specific and substantial are in fact set forth in the specification. For example, at page 22, paragraph [0077], Applicants point out that 69087 is a human GRK7 protein that can function as a G protein coupled receptor kinase. Furthermore, Applicants respectfully point out that specific diseases for treatment and/or diagnosis using the claimed nucleic acids, proteins encoded by the nucleic acids, or compounds identified in methods utilizing the claimed nucleic acids are in fact set forth in the specification. For example, at page 22, lines 11-17; at page 21, line 20 through page 22, line 1; and at page 23, lines 1-9, Applicants teach specific uses for diagnosis and treatment of certain vision-related and visual-signaling-related disorders and diseases (e.g., blindness, macular degeneration, retinitis pigmentosa, tumors of the eye). Applicants submit the utilities set forth for treatment and/or diagnosis using the claimed nucleic acids, proteins encoded by the nucleic acids, or using compounds identified in methods utilizing the claimed nucleic acids are also substantial utilities, since the asserted use to diagnose and/or treat specific diseases (e.g., blindness, macular degeneration, retinitis pigmentosa, tumors of the eye) using the provided compositions and methods utilizing such compositions constitutes a real world use. Thus, in contrast to the Examiner's assertions, Applicants submit a utility specific and substantial for nucleic acids encoding 69087 has in fact been asserted.

In order to rebut an asserted utility, an Examiner must: make a prima facie showing of no specific and substantial credible utility and the Examiner must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. See MPEP §2107 II (C) (2). The steps that should be taken in order to make an effective rejection should fall under MPEP 2107 (II)(C), where the Examiner is required to make a proper prima facie showing of no specific and substantial credible utility. See MPEP 2107(II)(C) (emphasis added):

*(1) Where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial.*

*The prima facie showing must contain the following elements:*

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- (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;*
- (ii) Support for factual findings relied upon in reaching this conclusion; and*
- (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.*

The Examiner has not made a sufficient supported showing to establish more likely than not the utility set forth in the present specification would not be specific, substantial or credible, as sufficient support or factual findings which relate to the present invention have not been relied upon to make such a showing to rebut Applicants' assertion that the use of the claimed compositions in diagnostics assays and/or identification of therapeutics in disorder of vision related and visual-signaling related disorders (e.g., blindness, macular degeneration, retinitis pigmentosa, tumors of the eye) would more likely than not be useful. Rather, the Examiner relies on general arguments and journal references which relate to distinct classes of proteins to purportedly demonstrate that no known function could be gleaned from structural similarity, and to back up the claim that Applicant's original assertion is neither specific nor substantial. For example, the Examiner cites Scott et al to stand for the premise that significant homology to known proteins cannot be determinative of function. However, Scott et al compares sulfate transporters which are only 29%-45% similar. Additionally, the Examiner relies on a number of general references which discuss structure based functional assignments are not always predictable.

Applicants point out the sequence homology of 69087 to GRK7 proteins as indicated in Figure 3 and discussed in the specification is very high with regard to mammalian GRK7 proteins: 99.5% to the human SGK064 sequence (disclosed in the PCT application having publication number WO 01/38503), and 85.2% to the ground squirrel GRK7. The sequence of 69087 is also highly homologous to the medaka fish and carp GRK7 proteins (OL GRK7 and CC GRK7 in Figure 3), having 60.6% and 59.5% identity, respectively. Furthermore, the general references discussed by the Examiner do not point to any specific deficiency that Applicants assertion is invalid, incorrect, flawed reasoning, or otherwise. Applicants submit the Examiner has not met the requisite requirement to rebut Applicants asserted utility – no evidence specific to demonstrate Applicants' asserted utility is inoperative, not useful, or contradictory to scientific principles has been presented. The articles relied on are either entirely unrelated to the present invention and the class of molecules to which it belongs, or they are so general and raise a question that in some situations function is not predictable based on structure alone. However, this is not sufficient for one skilled in the art to believe that more likely than not Applicants' asserted utility is not credible.

Even assuming arguendo that the Examiner has made a proper rejection, Applicants submit that supporting evidence weighs in favor of supporting Applicants' asserted utility. For example, at page 22,

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lines 12-16, and in IDS citations C1 and C2 (Weiss et al. 2001, Journal of Neuroscience 21(23):9175-9184; and Chen et al 2001, Molecular Vision 7:305-313, respectively), Applicants point out that 69087 (AKA human GRK7) in fact is expressed in the retina and can phosphorylate cone opsins and rod opsins, and can function in one or more aspects relating to vision and visual signaling pathways. In addition, IDS citation C3 (Cideciyan et al. IOVS, March 2003, Vol. 44, No. 3 pp1268-1274) teaches that GRK7 is cone photoreceptor involved in maintenance of healthy deactivation kinetics in human cone cells. Thus, the evidence weighs in favor of Applicants' original assertion of utility. As such, maintenance of the utility rejection as non-credible is improper.

In sum, Applicants submit an effective, specific, substantial, credible utility has been properly asserted in the specification as filed. Applicants respectfully believe the Examiner's imposition of the present rejection is improper in view of the utility guidelines and MPEP §2701, because a prima facie rebuttal of the asserted utility has not been properly effected. Furthermore, even if a prima facie case had been supported, Applicants contend the evidence weighs in favor of support of the asserted utility. Therefore, Applicants respectfully believe the Examiner's imposition of the present rejection is improper in view of the utility guidelines and MPEP §2701, and as such the rejection under 35 USC §101 should be withdrawn.

**Rejection of Claims 76-82 under 35 USC §112, first paragraph, Should Be Withdrawn**

Claims 76-82 were rejected under 35 USC §112, first paragraph due to lack of satisfying the utility requirement. For the reasons discussed above, Applicants submit the utility requirement has been met and respectfully request reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph.

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## CONCLUSIONS

In view of the remarks herein, Applicants respectfully submit that the objections and rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

This paper is being filed timely as a request for a two month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

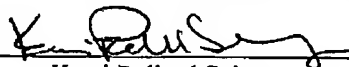
Entry of the remarks made herein is respectfully requested.

February 23, 2005

Respectfully submitted,

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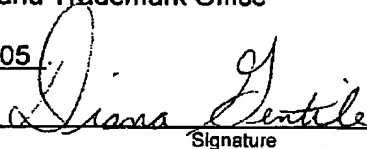
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Amendment Transmittal

(2 pages—in duplicate)

Response

(7 pages)

Total

Pages (12 pages)  
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